

REMARKS

Claims 1, 4-6, 8-16 and 20-22 are pending in the present application, which is directed to methods for detecting the effect of test conditions on a eukaryotic cell culture. The present invention may be used, for example, to screen agents for their effect on eukaryotic cells and thereby identify potential anticancer drugs for use in humans and animals. The present invention may also be used in toxicology assays to help determine the toxicity of an agent in humans and animals. Claims 2, 3, 7, 17-19 and 23 have been cancelled and claims 1, 4, 8-11, 12 and 20 are currently amended. Favorable consideration of the currently pending claims is respectfully requested in light of these amendments and the following remarks.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-22 under 35 U.S.C. § 103(a) as being unpatentable over Squirrell (U.S. Patent No. 5,648,232) in view of Webster's Dictionary (1984). More specifically, the Examiner stated that U.S. Patent No. 5,648,232 (hereinafter the '232 patent) discloses a method for detecting the presence and/or amount of microorganisms by estimating the amount of adenylate kinase. The Examiner further stated that the '232 patent does not disclose the use of eukaryotic cells, but that Webster's dictionary definition of "microorganism" encompasses the eukaryotic cells in the sample of the present invention. Applicants respectfully traverse the rejection.

The claimed invention is directed to an assay for determining the effect of test conditions on the integrity of eukaryotic cells in a cell culture. In other words, the present claimed invention is directed to monitoring the impairment of eukaryotic cells upon subjecting them to test conditions. The claimed methods can be used to determine the degree of eukaryotic cell lysis caused by the test condition and to determine whether the eukaryotic cells subjected to the test conditions are growing and dividing normally.

These particular embodiments are described on at least page 6, lines 16-37 and page 8, lines 11-37, respectively, of the present application.

Test conditions are described at least on page 6, lines 26-37, and include chemical, biological and biochemical agents as well as temperature, pH, pressure, and irradiation. The effect of the test condition is determined by adding ADP to the eukaryotic cell sample subjected to the test condition, detecting ATP in the sample and correlating the ATP detected to the presence of adenylate kinase. The cells may or may not be lysed prior to the addition of ADP. The presence of adenylate kinase indicates the test condition's effect on the integrity of the eukaryotic cell.

The present invention may be used, for example, to screen agents for their effect on eukaryotic cells and thereby identify potential anticancer drugs for use in humans and animals. In one embodiment as represented in claim 1, the eukaryotic cell culture is subjected to a test condition followed by the addition of ADP to the cells. An increase in adenylate kinase in the sample, as compared to an untreated sample, indicates that the test condition had an effect on the eukaryotic cell integrity. When the test condition is a compound, an increase in adenylate kinase indicates that the compound is a good drug candidate. Importantly, the invention embodied in claim 1 does not require the complete lysis of the eukaryotic cells. The present invention allows for detection of impairment of eukaryotic cell integrity in the form of lysis or partial lysis.

In contrast to the present invention, the '232 patent merely describes a method for detecting the presence and/or amount of microorganisms in a sample by lysing the microorganisms with, for example, detergent or mechanical means and detecting the amount of ATP in the sample after adding ADP thereto. According to the '232 patent, all of the adenylate kinase associated with the microorganism should be rendered available to the ADP. (See Column 5, lines 25-34.) There is no teaching or suggestion anywhere in the '232 patent that the assays described therein could be used for any other purpose than detecting the presence or amount of a microorganism in a sample by completely lysing the microorganisms in the sample. More importantly, there is no teaching or

suggestion that the methods described in the '232 patent could be used to determine the cell integrity, including partial lysis, of a eukaryotic cell subjected to a test condition.

While another embodiment of the present invention as represented in claim 11 does require lysis of the eukaryotic cells, such lysis occurs only after the cells have been subjected to a test condition. Accordingly, the amount of adenylate kinase present again indicates whether the test condition has had an impact on the growth of the eukaryotic cells. The '232 patent does not teach or suggest the use of a test condition in addition to the use of a lytic agent, and therefore, does not teach or suggest a method of determining the effect of a test condition on eukaryotic cell integrity. The '232 patent teaches a method for determining the amount or presence of a microorganism and is not concerned with a method to determine whether a microorganism or eukaryotic cell is growing and dividing normally.

Applicants respectfully submit that determining the effect of test conditions on eukaryotic cell integrity is very different from detecting the presence and/or amount of a microorganism in a sample. The assay claimed in the present application is in the field of biochemical and pharmaceutical research, and more particularly, the screening of pharmaceuticals, whereas the assay disclosed in the '232 patent is for the detection of harmful bacteria in the very different field of hygiene monitoring and microorganism detection, useful in areas such as food and water safety. Therefore, one would not be motivated to look to the '232 patent to find a solution to the problems commonly associated with biochemical and pharmaceutical research on eukaryotic cells. Accordingly, Applicants request that the Examiner review and withdraw the rejection.

Conclusion

Based upon the amendments and remarks provided above, Applicants believe that Claims 1, 4-6, 8-16 and 20-22 are in condition for allowance. A Notice of Allowance is therefore respectfully solicited. No fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855. If the Examiner believes any

SECOND AMENDMENT AND RESPONSE TO OFFICE ACTION

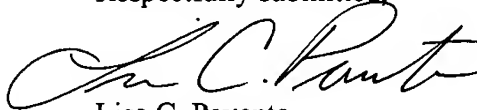
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informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 745-2517 is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lisa C. Pavento", written in a cursive style.

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